UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THEO CARAMIHAI, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. HELIUS MEDICAL TECHNOLOGIES, INC., PHILIPPE DESCHAMPS, JOYCE LAVISCOUNT and JONATHAN SACKIER Defendants.	Case No.: **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff Theo Caramihai ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Helius Medical Technologies, Inc. ("Helius" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Helius; and (c) review of other publicly available information concerning Helius.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that acquired Helius securities between November 9, 2017 and April 10, 2019, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Helius is a neurotechnology company that purports to develop, license, or acquire non-invasive technologies targeted at reducing symptoms of neurological disease or trauma. The Company's Portable Neuromodulation Stimulator ("PoNS") is purportedly a medical device for the treatment of chronic balance deficit associated with mild to moderate traumatic brain injury.

3. On January 25, 2019, the Company announced that it had received a request for additional data and information from the U.S. Food and Drug Administration (the "FDA") related to the Company's request for de novo classification and 510(k) clearance of PoNS.

4. On this news, the Company's share price fell $0.48, or approximately 6%, to close at $7.13 per share on January 25, 2019, on unusually heavy trading volume.[1]

5. On April 10, 2019, the Company revealed that the FDA had denied regulatory clearance of the PoNS device because the Company had not provided sufficient clinical data to show the device was effective.

[1] The Company's stock traded on a split-adjusted basis following a one-for-five reverse stock split, effective January 23, 2018. All references to the stock price herein reflect the post-split price.

6. On this news, the Company's share price fell $4.11, or more than 66%, to close at $2.10 per share on April 10, 2019, on unusually heavy trading volume.

7. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the clinical study on the use of PoNS did not produce statistically significant results regarding the effectiveness of the treatment; (2) that, as a result, the clinical study did not support the Company's application for regulatory clearance; (3) that, as a result, the Company was unlikely to receive regulatory approval of PoNS; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially false and/or misleading and/or lacked a reasonable basis.

8. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

9. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

11. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District, including at investor conferences held in this Judicial District.

12. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the

United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

13. Plaintiff Theo Caramihai, as set forth in the accompanying certification, incorporated by reference herein, purchased Helius securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

14. Defendant Helius is incorporated under the laws of Delaware. Helius's common stock trades on the NASDAQ exchange under the symbol "HSDT."

15. Defendant Philippe Deschamps ("Deschamps") was the Chief Executive Officer ("CEO") of the Company at all relevant times.

16. Defendant Joyce LaViscount ("Viscount") was the Chief Financial Officer and Chief Operating Officer of the Company at all relevant times.

17. Defendant Jonathan Sackier ("Sackier") was the Chief Medical Officer of the Company at all relevant times.

18. Defendant Deschamps, LaViscount and Sackier are also referred to hereinafter as the "Individual Defendants." Defendants Deschamps, LaViscount and Sackier because of their position with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to her, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

19. Helius is a neurotechnology company that purports to develop, license, or acquire non-invasive technologies targeted at reducing symptoms of neurological disease or trauma. The Company's Portable Neuromodulation Stimulator ("PoNS") is purportedly a medical device for the treatment of chronic balance deficit associated with mild to moderate traumatic brain injury.

Materially False and Misleading Statements Issued During the Class Period

20. The Class Period begins on November 9, 2017. On that day, the Company announced positive results from its clinical trial evaluating the safety and effectiveness of the PoNS for traumatic brain injury. In a press release, the Company stated, in relevant part:

Study results highlights:

- Primary effectiveness endpoint demonstrated a trend toward a higher responder rate in the high frequency PoNS™ Therapy group (75.4%) than in the low frequency PoNS™ Therapy group (60.7%), p<0.081
    - Primary effectiveness endpoint was not reached because low frequency pulse treatment had a significant therapeutic effect
- Secondary effectiveness endpoints demonstrated statistically and clinically significant increases (at least 8 points) in composite SOT scores:
    - The mean improvement at 2 weeks for combined-arms was 18.3 points, p<0.0005
    - The mean improvement at 5 weeks for combined-arms was 24.6 points, p<0.0005
- Successfully met primary and secondary safety endpoints as measured by a decrease in falls and headaches, in both groups
- There were no serious device related adverse events

"We are very pleased with the findings from our registrational trial that demonstrate that PoNS™ Therapy, deployed independently across our seven study sites, ***produced statistically significant improvements in balance from baseline***, on average over three times the clinically significant amount," said Helius' Chief Medical Officer, Dr. Jonathan Sackier. "Achieving the safety endpoints and further growing a positive safety profile continues to build confidence in our technology. With an underserved patient population waiting for

> improved treatment opportunities, we are eager to move forward with our applications for clearance with the U.S. Food and Drug Administration (FDA) and other foreign regulatory bodies."

21. On November 17, 2017, the Company provided a clarification about the clinical results and plans for FDA submission, stating in a press release:

> Philippe Deschamps, Chief Executive Officer of Helius, stated, "The data showed participants who received PoNS Therapy experienced average SOT score improvements double to triple the increase that would be expected with physical therapy alone in a much shorter timeframe. The company is excited to finalize and submit its regulatory dossier to the FDA."
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> * * *
>
> **Plans for FDA Submission for Marketing Authorization**
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> First, it is critical to note that the planned route to market for the PoNS™ Therapy is as a class II medical device via the *de novo* classification process. This is novel technology for which there are currently no substantially equivalent devices being marketed in the US. During the pre-submission meeting with FDA, it was established that the investigational PoNS™ Therapy study to address balance symptoms in participants with mild to moderate TBI was a "Non-Significant Risk" device study.
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> FDA will evaluate the probable benefit to health from the use of the device against any probable injury based upon a reasonable assurance of safety and effectiveness. There is a reasonable assurance that a device is effective when it can be determined by FDA, based upon valid scientific evidence, that in a significant portion of the target population, the intended use of the device will provide clinically significant results. We believe we have met this standard in the results of the two clinical trials reported on in this communication in participants that had significant balance disorder associated with their mild to moderate TBI.
>
> Second, the treatment of balance disorder after TBI is a significant health issue and represents an unmet medical need. We believe the results of these two clinical trials indicate that the investigational PoNS™ Therapy represents a promising opportunity to help patients and address a recognized unmet medical need.
>
> Helius also has accomplished the following steps to securing marketing authorization:
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> 1. *Proven Quality Management Systems.* The company obtained ISO 13485 certification in October 2016 . . . and in September, 2017 passed their annual audit with no issues. Helius has therefore satisfied this element.

2. *Design Verification:* The company is engaged in a battery of tests to ensure the investigational PoNS™ device can be manufactured to the required quality. These tests, once successfully completed, will accompany submission to FDA.

22. On June 18, 2018, the Company announced that it had engaged in pre-submission meetings with the FDA to support its 510(k) application. In a press release, the Company stated, in relevant part:

> "As part of the submission process for de novo classification and 510(k) clearance, FDA encourages companies to engage in pre-submission meetings to obtain the Agency's perspective and feedback," stated Jonathan Sackier, Helius' Chief Medical Officer. "***The breakthrough nature of our PoNS technology heightens the Company's desire to work closely with FDA in advance of our submission. We have thus proactively engaged in FDA's Pre-Submission Program to reduce the likelihood of questions from FDA during their review of the PoNS 510(k) submission***."
>
> Dr. Sackier continued: "We met with FDA in a pre-submission meeting held in April, which focused on the design verification testing used to support our submission. ***We believe this meeting was very productive and we adjusted this element of our submission to incorporate feedback from FDA. We are scheduled to meet with FDA again in July and expect this meeting to be equally productive***. Given the timing of this pre-submission meeting, we now expect to submit our request for de novo classification and 510(k) clearance in the third quarter of 2018."
>
> "The submission of our request for FDA clearance of the PoNS device for the treatment of chronic balance deficit due to mild- to moderate-traumatic brain injury is an important milestone for Helius, which the Company has been working towards since we began our registrational clinical trial in 2015," added Philippe Deschamps, Helius' President, CEO and Chairman. "We are excited about our data and continued collaboration with FDA to finalize our full submission package."

(Emphasis added.)

23. On September 4, 2018, the Company announced that it had submitted its request for de novo classification and 510(k) clearance of the PoNs device. In a press release, the Company stated, in relevant part:

> "Helius is excited to announce the submission of our request for de novo classification and 510(k) clearance of the PoNS device for the treatment of chronic balance deficit due to mild- to moderate-traumatic brain injury," said Philippe Deschamps, Helius' President, CEO and Chairman. "This important milestone is the result of many years of hard work from the Helius team, and it brings us one step closer to making our novel PoNS Treatment available for U.S.

> patients who suffer from the potentially disabling effects of TBI-related chronic balance disorder."
>
> ***The Company's request for de novo classification and 510(k) clearance is supported by clinical data from two double-blind, randomized, controlled trials demonstrating the PoNS device's safety and efficacy, with combined enrollment of 163 patients. It is also informed by feedback provided by FDA during pre-submission meetings that focused on the Company's trial designs, clinical data and design verification testing.***
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> Mr. Deschamps continued: "Looking ahead, the Company is focused on laying the groundwork for the commercial launch of our PoNS Treatment following FDA clearance and pursuing regulatory clearances in Canada, Australia, Europe."

(Emphasis added.)

The Truth Begins to Emerge

24. The truth begins to emerge on January 25, 2019 when the Company announced that it had received a request for additional information from the U.S. Food and Drug Administration (the "FDA") related to the Company's request for de novo classification and 510(k) clearance. In a press release, the Company stated, in relevant part:

> During the substantive review phase of a request for De Novo classification and 510(k) clearance, FDA may request additional information in order to obtain information necessary for the agency to continue or complete its review and, in such instances, places its review on hold until the requested information is submitted.
>
> "We have enjoyed a good relationship with FDA in the development and review of our file. ***We believe we have the data and information to address FDA's questions and we look forward to submitting our response to enable FDA to resume its review process as expeditiously as possible***," said Philippe Deschamps, Helius' Chief Executive Officer. "We will continue to work towards securing clearance of PoNS."
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> Mr. Deschamps continued: "The PoNS device is a novel technology and our pursuit of a clearance is focused on providing a solution for patients suffering from chronic balance deficit due to mild-to-moderate traumatic brain injury, a condition that impacts more than two million people in the United States. We understand and appreciate the thorough and detailed approach the FDA has taken to learn about our novel technology. We look forward to receiving clearance in the United States for our non-invasive treatment of chronic balance deficit due to mild-to-moderate traumatic brain injury."

(Emphasis added.)

25. On this news, the Company's share price fell $0.48, or approximately 6%, to close at $7.13 per share on January 25, 2019, on unusually heavy trading volume.

26. The above statements identified in ¶¶20-24 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the clinical study on the use of PoNS did not produce statistically significant results regarding the effectiveness of the treatment; (2) that, as a result, the clinical study did not support the Company's application for regulatory clearance; (3) that, as a result, the Company was unlikely to receive regulatory approval of PoNS; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially false and/or misleading and/or lacked a reasonable basis.

Additional False and Misleading Statements At The Oppenheimer Healthcare Conference

27. On March 20, 2019, the Individual Defendants participated in the Oppenheimer Healthcare Conference held in New York, New York. Defendant Deschamps described the FDA regulatory approval process for the Company's PoNS system, stating in relevant part:

> So here's where we are from a regulatory standpoint in the U.S., we submitted to FDA at the end of August on - as part of the User Fee Act, FDA strives to get back to people within 150 days. Day 142 or so, they got back to us and gave us a request for additional information. Certainly not uncommon for breakthrough kind of therapies that they've never reviewed before. Our submission path was a de novo to 510(K), and by de novo means that they have never reviewed anything like this before. And I can qualitatively describe the questions that they asked as fair, based on a novel therapy being in front of them for the first time. I can also qualify them as comprehensive, meaning that it gave us the impression. And certainly, our regulatory turned to the impression that they had looked at the whole submission and found all of the different elements from there. And they were specific. Where is this table? We didn't find this in your submission. Can you reanalyze this? Because we're curious about that kind of questions. Right. Very, very specific.
>
> We announced at our earnings call last Thursday that we had now answered the questions from FDA. So, they now have our answers and have picked up the file to review. And I wish there was a crystal ball that could allow me to tell you that it's going to be 10 days, 60 days, 180 days. We don't know. And certainly the dynamics at the beginning of the year where there was a government shutdown for 35 days. We have no idea what the impact of that is.

> So, your guess is as good as ours, although we are very confident that we answered every one of their questions, all right. It will be in their behalf whether they know.

28. The above statements identified in ¶27 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the clinical study on the use of PoNS did not produce statistically significant results regarding the effectiveness of the treatment; (2) that, as a result, the clinical study did not support the Company's application for regulatory clearance; (3) that, as a result, the Company was unlikely to receive regulatory approval of PoNS; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially false and/or misleading and/or lacked a reasonable basis.

The Truth Finally Emerges

29. On April 10, 2019, the Company revealed that the FDA had denied regulatory clearance of the PoNS device because the Company had not provided sufficient clinical data to show the device was effective. In a press release, the Company stated, in relevant part:

> In reaching its conclusion, the Agency noted that it did not have sufficient information to discern the relative independent contributions of the PoNS Device and physical therapy on the improvements from baseline in the effectiveness endpoints observed in the Company's clinical studies. The FDA noted that the Company could generate additional data to address its concerns and resubmit its application.
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> In the course of its review of the Company's submission, the Agency recognized that there were no device-related serious adverse events in either of the Company's two clinical trials, and that patients in both the treatment and the sham control arms demonstrated improvements from baseline for all the pre-specified clinical endpoints, including the primary endpoint of responder rate based on Sensory Organization Test score.
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> "We are understandably disappointed by the Agency's decision to decline our request for De Novo classification and 510(k) clearance, but Helius remains committed to generating the data to pursue a De Novo classification and 510(k) clearance of our PoNS device in the future for the treatment of patients with chronic balance deficit due to mmTBI, in order to bring our innovative therapy to more than 1.5 million Americans suffering from this condition," said Philippe Deschamps, Chief Executive Officer of Helius. "In addition to working on

> generating this new data, we will continue to focus on expanding our commercial efforts and treating patients in Canada, where we do currently have regulatory clearance," added Mr. Deschamps.

30. On this news, the Company's share price fell $4.11, or more than 66%, to close at $2.10 per share on April 10, 2019, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

31. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that acquired Helius securities between November 9, 2017 and April 10, 2019, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

32. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Helius's common stock actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Helius common stock were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Helius or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

33. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

34. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

35. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the

questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Helius; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

36. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

37. The market for Helius's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Helius's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Helius's securities relying upon the integrity of the market price of the Company's securities and market information relating to Helius, and have been damaged thereby.

38. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Helius's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Helius's business, operations, and prospects as alleged herein.

39. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Helius's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

40. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

41. During the Class Period, Plaintiff and the Class purchased Helius's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

42. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of his receipt of information reflecting the true facts regarding Helius, his control over,

and/or receipt and/or modification of Helius's allegedly materially misleading misstatements and/or his associations with the Company which made them privy to confidential proprietary information concerning Helius, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE
(FRAUD-ON-THE-MARKET DOCTRINE)

43. The market for Helius's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Helius's securities traded at artificially inflated prices during the Class Period. On November 9, 2017, the Company's share price closed at a Class Period high of $14.00 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Helius's securities and market information relating to Helius, and have been damaged thereby.

44. During the Class Period, the artificial inflation of Helius's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Helius's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Helius and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

45. At all relevant times, the market for Helius's securities was an efficient market for the following reasons, among others:

(a) Helius shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Helius filed periodic public reports with the SEC and/or the

NASDAQ;

(c) Helius regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Helius was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

46. As a result of the foregoing, the market for Helius's securities promptly digested current information regarding Helius from all publicly available sources and reflected such information in Helius's share price. Under these circumstances, all purchasers of Helius's securities during the Class Period suffered similar injury through their purchase of Helius's securities at artificially inflated prices and a presumption of reliance applies.

47. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

48. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and

conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Helius who knew that the statement was false when made.

FIRST CLAIM
Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder
Against All Defendants

49. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

50. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Helius's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

51. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Helius's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

52. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Helius's financial well-being and prospects, as specified herein.

53. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Helius's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Helius and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

54. The Individual Defendants's primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or director at the Company during the Class Period and member of the Company's management team or had control thereof; (ii) the Individual Defendants by virtue of their responsibilities and activities as senior officers and/or directors of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) the Individual Defendants enjoyed significant personal contact and familiarity with the other defendants and were advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) the Individual Defendants were aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

55. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to

ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Helius's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

56. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Helius's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Helius's securities during the Class Period at artificially high prices and were damaged thereby.

57. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Helius was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Helius securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

58. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

59. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM
Violation of Section 20(a) of The Exchange Act
Against the Individual Defendants

60. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

61. The Individual Defendants acted as controlling persons of Helius within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

62. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

63. As set forth above, Helius and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling person, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the

Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: July 9, 2019

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Attorneys for Plaintiff

SWORN CERTIFICATION OF PLAINTIFF

HELIUS MEDICAL TECHNOLOGIES, INC. SECURITIES LITIGATION

I, Theo Caramihai, individually, and/or in my capacity as trustee and/or principal for accounts listed on Schedule A, certify that:

1. I have reviewed the Complaint and authorize its filing and/or the filing of a Lead Plaintiff motion on my behalf.

2. I did not purchase the Helius Medical Technologies, Inc. securities that are the subject of this action at the direction of plaintiff's counsel or in order to participate in any private action arising under this title.

3. I am willing to serve as a representative party on behalf of a class and will testify at deposition and trial, if necessary.

4. My transactions in Helius Medical Technologies, Inc. securities during the Class Period set forth in the Complaint are as follows:

   (See attached transactions)

5. I have not sought to serve, nor served, as a representative party on behalf of a class under this title during the last three years, except for the following:

6. I will not accept any payment for serving as a representative party, except to receive my pro rata share of any recovery or as ordered or approved by the court, including the award to a representative plaintiff of reasonable costs and expenses (including lost wages) directly relating to the representation of the class.

I declare under penalty of perjury that the foregoing are true and correct statements.

7/8/2019
Date

DocuSigned by:
Theo Caramihai
A442899C8ACC4C5...
Theo Caramihai

Theo Caramihai's Transactions in Helius Medical Technologies, Inc. (HSDT)

Date	Transaction Type	Quantity	Unit Price
12/12/2017	Bought	4,000	$2.4090

*Share quantity and price have been adjusted following Helius Medical Technologies, Inc. 1-for-5 reverse stock split of its outstanding Class A common stock on January 23, 2018